

EXHIBIT 2



**ASTRAZENECA AB, AKTIEBOLAGET HASSLE, KBI-E INC., KBI, INC., and
ASTRAZENECA, LP, Plaintiffs, v. APOTEX CORP., APOTEX, INC. and
TORPHARM, INC., Defendants. IN RE OMEPRAZOLE PATENT LITIGATION**

01 Civ. 9351

**UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF
NEW YORK**

2010 U.S. Dist. LEXIS 58044

June 8, 2010, Decided

June 9, 2010, Filed

PRIOR HISTORY: *Astrazeneca AB v. Mylan Labs., Inc. (In re Omeprazole Patent Litig.)*, 490 F. Supp. 2d 381, 2007 U.S. Dist. LEXIS 39670 (S.D.N.Y., 2007)

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JUDGES: Barbara S. Jones, UNITED STATES DISTRICT JUDGE.

OPINION BY: Barbara S. Jones

OPINION

***Opinion* [*6] & Order**

BARBARA S. JONES

UNITED STATES DISTRICT JUDGE

On December 12, 2008, Apotex Corp., Apotex, Inc. and Torpharm, Inc. ("Apotex") filed a motion for judgment on the pleadings pursuant to *Federal Rule of Civil Procedure 12 (c)* as to AstraZeneca AB, Aktiebolaget Hassle, KBI-E, Inc., KBI, Inc., and AstraZeneca, LP's ("Astra") Claims for Willful

Infringement and Increased Damages. For the reasons set forth below, Apotex's motion is GRANTED.

BACKGROUND

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1 For a more complete recitation of the facts and procedural history of this case, the reader is directed to the Court's decision dated May 31, 2007. *See AstraZeneca AB, et al. v. Mylan Labs., Inc.*, 490 F. Supp. 2d 381 (S.D.N.Y. 2007).

In 2001, Apotex submitted an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration seeking approval to manufacture and market its omeprazole products before the expiration of U.S. Patent Nos. 4, 786, 505 (the "'505 patent'") and 4,853, 230 (the "'230 patent'"). In the ANDA, Apotex certified that the '505 and '230 patents were invalid or would not be infringed by Apotex's products. In April 2001, Astra filed a patent infringement suit against Apotex pursuant to 35 U.S.C. § 271(e) (2) (A) [*7] based on Apotex's ANDA, alleging that Apotex's omeprazole products would infringe the asserted claims of the '505 and '230 patents. The filing of Astra's complaint triggered an automatic 30-month stay. *See* 21 U.S.C. § 355 (j) (5) (B) (iii).

In October 2003, the FDA granted final approval for Apotex's ANDA and the automatic stay expired. (Second Am. Compl., April 6, 2005, at PP 24a, 36a.) On or about November 12, 2003, Apotex began selling its omeprazole products. Astra did not seek a preliminary injunction. However, on March 4, 2005, Astra moved to amend its complaint to include facts relating to Apotex's sale of omeprazole products in the United States and to add claims for willful infringement and increased damages. The Court granted Astra's motion to amend and on April 6, 2005, Astra filed its Second Amended Complaint. The Second Amended Complaint alleges that Apotex's acts of infringement were willful and deliberate. (*Id.* PP 24e, 36e.) It also asserts that the case is exceptional under 35 U.S.C. § 285 based on Apotex's "lack of a meritorious defense and [Apotex's] litigation misconduct." (*Id.* PP 25, 37.)

The Court bifurcated the case, considering separately (i) liability and (ii) [*8] damages and willfulness. In 2006, the Court held a 42-day bench trial on liability, which involved "weeks of trial testimony, volumes of

depositions, [and] thousands of exhibits." *AstraZeneca AB, et al. v. Mylan Labs., Inc.*, 490 F. Supp. 2d 381 (S.D.N.Y. 2007). During the trial, the Court considered evidence regarding whether Apotex's omeprazole products had a third layer that formed *in situ* after manufacturing (as the patents-in-issue require that an omeprazole tablet have three layers to be infringing). *Id.* at 474-83. On May 31, 2007, in its Second Wave Opinion, the Court concluded that Apotex's omeprazole products infringed claims 1, 5, 6, and 10 of the '505 patent and claims 1, 6, 7, and 13 of the '230 patent. *Id.* at 486. The Federal Circuit affirmed those findings. *See In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008). Meanwhile, the patents-in-issue expired on April 20, 2007. According to Astra, Apotex continued its infringing activity until at least June 18, 2007, when the Court entered its order pursuant to the Second Wave Opinion.

Apotex now moves for judgment on the pleadings, arguing that Astra cannot obtain enhanced damages for willful infringement because (1) [*9] Astra failed to seek a preliminary injunction after the 30-month stay expired, as required by *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc) ("*Seagate*"), and (2) Astra cannot establish that Apotex acted with objective recklessness in manufacturing and marketing its omeprazole products.

LEGAL STANDARD

"The test for evaluating a [Fed. R. Civ. P.] 12(c) motion is the same as that applicable to a motion to dismiss under Fed. R. Civ. Proc. 12(b)(6)." *Irish Lesbian & Gay Org. v. Giuliani*, 143 F.3d 638, 644 (2d Cir. 1998). Therefore, the Court must "accept all factual allegations in the complaint as true and draw all reasonable inferences in [the non-movant's] favor." *Johnson v. Rowley*, 569 F.3d 40, 44 (2d Cir. 2009). To survive the 12(c) motion, the complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, U.S. , 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)).

As with a Rule 12(b)(6) motion, Rule 12(c) motions are limited to the facts alleged in the complaint. However, in the course of its review, the Court may refer "to documents [*10] attached to the complaint as an exhibit or incorporated in it by reference, to matters of

which judicial notice may be taken, or to documents either in plaintiffs' possession or of which plaintiffs had knowledge and relied on in bringing suit." *Brass v. Am. Film Tech., Inc.*, 987 F.2d 142, 150 (2nd Cir. 1993) (citation omitted).

DISCUSSION

Astra alleges that Apotex's acts of infringement were willful and deliberate, and that the case is exceptional under 35 U.S.C. § 285 due to Apotex's "lack of a meritorious defense and [Apotex's] litigation misconduct." (Second Am. Compl., April 6, 2005, at PP 24e, 25, 36e, 37.) In its motion for judgment on the pleadings, Apotex asserts that Astra cannot obtain enhanced damages for infringement as a matter of law for two reasons. First, Astra failed to seek a preliminary injunction after the 30-month stay expired, as required by the Federal Circuit in *Seagate*. See *Seagate*, 497 F.3d at 1374. And second, Apotex contends that Astra cannot establish that Apotex acted with objective recklessness in manufacturing and marketing its omeprazole products. (Apotex's Reply in Supp. of Rule 12(c) Motion for Judgment on the Pleadings 9-10.)

I. Preliminary Injunction

The [*11] Court turns first to Apotex's argument that Astra's failure to seek a preliminary injunction bars its willfulness claim.² In *Seagate*, the en banc Federal Circuit revised the standard for willful infringement, overruling *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983), which held that where "a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing." *Id.* at 1389-90. *Seagate* held that "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness," i.e., "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Id.* at 1371. The Court explained that "[t]he state of mind of the accused infringer is not relevant to this objective inquiry" but that, "[i]f this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have [*12] been known to the accused infringer." *Id.*

2 Although the Court decides this motion on a different basis, it considers this argument because the Parties devote considerable attention to it in their briefs.

The Federal Circuit also held in *Seagate* that a party's assertion of the advice of counsel defense to willful infringement does not waive the attorney-client privilege with respect to communications with that party's trial counsel (as opposed to opinion counsel). In reaching this holding, the Federal Circuit commented that "in ordinary circumstances, willfulness will depend on an infringer's prelitigation conduct," since a patentee must have a good faith basis to allege willful infringement when it files its complaint. *Id.* at 1374. The Court continued:

By contrast, when an accused infringer's post-filing conduct is reckless, a patentee can move for a preliminary injunction, which generally provides an adequate remedy for combating post-filing willful infringement. *A patentee who does not attempt to stop an accused infringer's activities in this manner should not be allowed to accrue enhanced damages based solely on the infringer's post-filing conduct.* Similarly, if a patentee attempts [*13] to secure injunctive relief but fails, it is likely the infringement did not rise to the level of recklessness.

We fully recognize that an accused infringer may avoid a preliminary injunction by showing only a substantial question as to invalidity, as opposed to the higher clear and convincing standard required to prevail on the merits. . . . However, . . . [a] substantial question about invalidity or infringement is likely sufficient not only to avoid a preliminary injunction, but also a charge of willfulness based on post-filing conduct.

Id. (internal citations omitted; emphasis added).

Apotex relies on the highlighted portion of this passage to argue that Astra cannot obtain enhanced damages for infringement that occurred after the filing of its complaint because Astra never sought a preliminary

injunction. Apotex reasons that Astra's damages accrued *after* it brought suit: Astra sued Apotex for patent infringement in April 2001 but Apotex did not sell any omeprazole products until November 2003. In Apotex's view, Astra's additional remedy for any allegedly reckless post-filing conduct by Apotex was a preliminary injunction. (Apotex's Mem. in Support of *Rule 12 (c)* Motion for Judgment [*14] on the Pleadings 8.)

The Court is not persuaded by this argument and does not rely on it in granting Apotex's motion for judgment on the pleadings. First, it is unlikely that *Seagate's* discussion of the necessity of a preliminary injunction applies retroactively. While the Federal Circuit held in *Voda v. Cordis Corp.*, 536 F.3d 1311, 1328 n. 10 (Fed. Cir. 2008) that *Seagate* does apply retroactively, that decision dealt with the retroactivity of the objective recklessness standard, not the requirement of obtaining a preliminary injunction. *See id. at 1328 & n.10* (rejecting plaintiff's argument that while the jury instruction on the standard for willfulness was erroneous under *Seagate*, that decision should not be applied retroactively). Apotex began selling its omeprazole products in November of 2003. *Seagate* was decided in August of 2007. It is one thing to apply *Seagate's* objective recklessness standard retroactively and quite another to bar Astra's willful infringement claim as a matter of law because Astra did not seek a preliminary injunction that it had no reason to believe was required.

In addition, in the context of this case, the "filing" to which *Seagate* refers when it says that [*15] a preliminary injunction must be filed to stop an infringer's "post-filing" conduct is not the original complaint but rather the Second Amended complaint; it is only in the latter pleading that Astra alleges willful infringement. *See Seagate*, 497 F.3d at 1374 ("A patentee who does not attempt to stop an accused infringer's activities [by moving for a preliminary injunction] should not be allowed to accrue enhanced damages *based solely on the infringer's post-filing conduct*") (emphasis added). Understood this way, the Court agrees with Astra that its willfulness claim is *not* based solely on Apotex's "post-filing" conduct. (Astra's Mem. in Opp. to Apotex's *Rule 12(c)* Motion for Judgment on the Pleadings 16.) It is alleged that Apotex willfully infringed Astra's patent by selling its omeprazole products beginning on November 12, 2003, which is almost a year and a half before Astra filed its Second Amended Complaint alleging willful infringement. Therefore, Astra's claims

for willful infringement are not "based solely on the infringer's post-filing conduct." *Seagate*, 497 F.3d at 1374. Rather, they are based on Apotex's conduct prior to the filing of Astra's Second Amended Complaint. For [*16] this reason, *Seagate's* requirement of a preliminary injunction does not apply.

Because Astra's failure to seek a preliminary injunction does not preclude its willful infringement claims as a matter of law, the Court turns to Apotex's alternative basis for judgment on the pleadings.

II. Objective Recklessness

As discussed above, under *Seagate* "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness," i.e., "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Seagate*, 497 F.3d at 1371. "The state of mind of the accused infringer is not relevant to this objective inquiry." *Id.* "If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." *Id.* Also as discussed, the objective recklessness standard applies retroactively. *See Voda*, 536 F.3d at 1328 n.10.

In its Second Amended Complaint, Astra alleges [*17] that Apotex's acts of infringement were willful and deliberate, and that the case is exceptional. (Second Am. Compl., April 6, 2005, at PP 24e, 25, 36e, 37.) Astra asserts that Apotex elected to sell its omeprazole products despite knowing about Astra's patents and despite submitting an ANDA certification that failed to provide a detailed statement of the factual and legal basis for its opinion that Astra's patents were invalid or not infringed. (Astra's Mem. in Opp. to Apotex's *Rule 12(c)* Motion for Judgment on the Pleadings 12.) Astra further claims that Apotex marketed its product in intentional disregard of the Court's First Wave claim construction and findings regarding *in situ* subcoatings. Specifically, Astra argues that after this Court's First Wave Opinion found that the patent claims include products in which the subcoating was formed *in situ*, *see Astra Aktiebolag v. Andrx. Pharms., Inc.*, 222 F. Supp. 2d 423, 469-70 (S.D.N.Y. 2002), Apotex wrongfully continued to maintain that its omeprazole products did not infringe because they lacked

a separately applied subcoating. (Astra's Mem. in Opp. to Apotex's *Rule 12(c)* Motion for Judgment on the Pleadings 3-4.) In Astra's view, [*18] Apotex "failed to go back after the First Wave Opinion and conduct an appropriate investigation into whether its products infringed in light of the First Wave claim constructions" and Apotex "disregarded well-known facts which would make any objective party acknowledge the objectively high risk that a subcoating formed in Apotex'[s] products and that absent further investigation there was an objectively high risk of infringement." (*Id.* at 6.) By adhering to the *in situ* subcoating defense that had already been rejected by the Court (and the Federal Circuit) in the First Wave, Astra argues, Apotex "acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Seagate*, 497 F.3d at 1371.

Apotex contends that Astra cannot establish that Apotex acted with objective recklessness in manufacturing and marketing its omeprazole products because other generic manufacturers were found by this Court not to infringe the '505 and '230 patents; a lengthy trial was required to determine factual questions specific to Apotex's product that had not been resolved in the First Wave trial; and Astra never filed for summary judgment, indicating that even Astra believed [*19] Apotex's defenses raised genuine issues of material fact. (Apotex's Reply in Supp. of *Rule 12(c)* Motion for Judgment on the Pleadings 9-10.)

The Court agrees with Apotex. While Astra ultimately succeeded at trial, Apotex raised a substantial question of infringement, one that required "an exhaustive analysis" by the Court. *Honeywell Int'l. Inc. v. Universal Avionics Systems Corp.*, 585 F. Supp. 2d 636, 644 (D. Del. 2008) (finding that patent infringement defendant's "arguments were substantial, reasonable, and far from the sort of easily-dismissed claims that an objectively reckless infringer would be forced to rely upon"). As an initial matter, Apotex's mere "knowledge of [Astra's] patent [s] does not mean willfulness." *Id.* In addition, Apotex raised substantial questions of non-infringement that required sustained analysis by the Court. *See, e.g., AstraZeneca AB, et al. v. Mylan Labs., Inc.*, 490 F. Supp. 2d 381, 471-86 (S.D.N.Y. 2007) (analyzing Apotex's formulation in light of claims of the '505 and '230 patents). It is true that the Court adopted its prior ruling in the First Wave Opinion that "the product claims of the '505 and '230 Patents do not limit the

manner in which [*20] the product is made and cover subcoatings regardless of how they are formed--including subcoatings formed *in situ*." *Id.* at 474. But Astra still had to convince the Court that Apotex's omeprazole products had this subcoating. Astra did, but only after the Court considered a substantial amount of evidence. *See id.* at 483 (finding that six categories of evidence revealed the presence of a subcoating in Apotex's product). Moreover, the Court had to assess Apotex's good faith--albeit unsuccessful---defense that any detectable fluorescence was omeprazole degradation and therefore was outside the scope of the patent claims (as well as two other defenses interposed by Apotex). *See id.* at 478, 482-83 ("Apotex asserts that Plaintiffs have failed to meet their burden of proof to show that Apotex's product contains a subcoating because . . . (1) the fluorescing region is actually omeprazole; (2) even if t an MACP: PVP complex, it is formed during Dr. Davies acetone: IPA washing of the pellets and not during Apotex's enteric coating; and (3) even if MACP reacts with PVP during Apotex's coating process, the MACP-PVP complex is not a subcoating within the meaning of the patents because it does not [*21] separate the omeprazole from the enteric coating in Apotex's product."). Apotex thus raised legitimate, substantial questions of non-infringement and, as such, Apotex is entitled to judgment as a matter of law on Astra's willful infringement claims. *See Seagate*, 497 F.3d at 1374 ("A substantial question about . . . infringement is likely sufficient . . . to avoid . . . a charge of willfulness . . .").

To the extent that Astra also argues that Apotex's invalidity defenses were baseless, the Court disagrees. *See Astra's Mem. in Opp. to Apotex's Rule 12(c) Motion for Judgment on the Pleadings 10-11* (contending that "Apotex itself should have recognized the weak nature of its invalidity positions" because, *inter alia*, it failed to raise validity challenges in its ANDA certification, it raised validity challenges that had been rejected by the Court in the First Wave, it relied on references already rejected by the Court and Federal Circuit, and it did not address validity during appellate oral argument). Apotex raised at least five distinct bases of invalidity, many of which were not duplicative of issues resolved in the First Wave Opinion. While the Court ultimately held that the asserted [*22] claims of the '505 and '230 Patents were valid, Apotex raised a substantial question of invalidity, one that required an exhaustive analysis by the Court. *See AstraZeneca AB, et al. v. Mylan Labs., Inc.*, 490 F. Supp. 2d 381, 499-535 (S.D.N.Y. 2007). As such, Apotex is

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entitled to judgment as a matter of law on Astra's willful infringement claims. *See Seagate*, 497 F.3d at 1374 ("A substantial question about invalidity . . . is likely sufficient . . . to avoid . . . a charge of willfulness . . .

Therefore, the Court grants Apotex's motion for judgment on the pleadings.

CONCLUSION

For the reasons set forth above, Apotex's motion for judgment on the pleadings as to Astra's claims for willful infringement and increased damages is GRANTED.

SO ORDERED:

/s/ Barbara S. Jones

Barbara S. Jones

UNITED STATES DISTRICT JUDGE

Dated: New York, New York

June 8, 2010